

Notice of Allowability

Application No.

10/693,328

Examiner

Leslie A. Royds

Applicant(s)

BARRAS ET AL.

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the supplemental amendment filed 20 July 2006.
2. ☒ The allowed claim(s) is/are 1-20, 22-31 and 36-45.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 18 May 2006
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 03 October 2006
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Leslie A. Royds
Patent Examiner
Art Unit 1614

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mike Wesolowski on Tuesday, October 03, 2006.

The following amendments have been authorized:

In the Claims:

- (1) Claims 21, 32-35 and 46-73 are cancelled.
- (2) In claim 1, please delete the phrase "ascorbic acid, one or more salts of ascorbic acid or" from line 6 of the claim.
- (3) In claim 19, please add the phrase ---a mixture of--- before "ascorbic acid" in line 1 of the claim and replace the word "or" at line 1 of the claim with the word ---and---.
- (4) In claim 20, please add the phrase ---a mixture of--- before "ascorbic acid" in line 1 of the claim and replace the word "or" at line 1 of the claim with the word ---and---.
- (5) In claim 31, please replace the phrase "and/or" at line 2 of the claim with the word ---and---.

Examiner's Statement Regarding Reasons for Allowance

The present application is allowed pursuant to Applicant's remarks presented in the amendment and supplemental amendment of, respectively, May 18, 2006 and July 20, 2006, and interview of July 14, 2006. Patentable distinction over prior art colon cleansing compositions has been established in view of the following parameters, which are not taught or fairly suggested by the prior art: the osmolarity of the solution between 300-700 mOsm/kg coupled with the use of a *mixture* of ascorbic acid and one or more salts of ascorbic acid.

Regarding the osmolarity, prior art colon cleansing solutions were generally isotonic (approximately that of blood, i.e., 290 mOsm/kg) or super-hyperosmotic (2000+ mOsm/kg). Colon cleansing preparations with mild hyperosmolarity (i.e., 300-700 mOsm/kg) were not taught or suggested by the prior art at the time of the present invention. Furthermore, the state of the art was such that one of ordinary skill in the art would have expected significant water loss resulting in dehydration and significant alteration of serum electrolytes from solutions with an osmolarity of between 300-700 mOsm/kg.

However, Applicant has made an objective showing that not only is the claimed preparation effective for colon cleansing at 300-700 mOsm/kg, but it also shows unexpected effects, namely that 2 L of the claimed solution gives the same or better colon cleansing effects as 4 L of the prior art solutions in the absence of significant dehydration, significant derangement of serum electrolytes and increased palatability of the composition and, thus, increased patient compliance.

Regarding the use of a mixture of ascorbic acid and one or more salts of ascorbic acid, the prior art does not teach or fairly suggest the concomitant use of both ascorbic acid and one or more salts thereof. In fact, the state of the art at the time of the invention was such that only ascorbic acid or a salt thereof was used in the preparation of such a composition. However, Applicant has additionally shown that the combination of ascorbic acid and one or more salts thereof in the claimed composition provides an unexpected effect over prior art solutions, namely that the use of both the acid and the salt avoids derangement of serum bicarbonate levels, which causes electrolyte imbalance.

Furthermore, it is also noted that the gram amounts of the physical components (i.e., polyethylene glycol, ascorbic acid and one or more salts thereof, an alkali metal or alkaline earth metal sulphate) are significantly larger than those of prior art compositions such that the dosage amounts are neither anticipated nor rendered obvious.

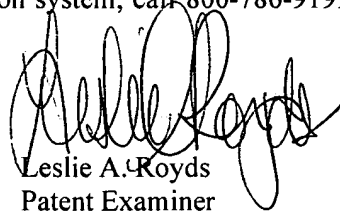
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For these reasons stated *supra* and those already presented in the record, the composition claims 1-31 and 36-45 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie A. Royds
Patent Examiner
Art Unit 1614

October 3, 2006



10/14/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER